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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/388,090

Applicant(s)
Jackson et al.

Examiner
S. Devi, Ph.D.

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1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 23, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-39, 48-52, and 56 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 and 56 is/are allowed.
- 6) ☒ Claim(s) 37, 39, and 48-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jan 23, 2003 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 29
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Sequence search reports (5)

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 01/23/03 (paper no. 28) in response to the Office Action mailed 06/20/2002 (paper no. 23). With this, Applicants have amended the specification. It is noted that new claim 56 presented on page 7 of the amendment is inconsistent with claim 56 provided in Appendix D.

Status of Claims

2) Claims 53-55 have been canceled via the amendment filed 01/23/03.
Claims 37-39 have been amended via the amendment filed 01/23/03.
New claim 56 has been added.
Claims 37-39, 48-52 and 56 are pending and are under examination.

Supplemental Information Disclosure Statement

3) Acknowledgment is made of Applicants' supplemental Information Disclosure Statement filed 03/06/03 (paper no. 29). The information referred to therein has been considered and a signed copy of the same is attached to this Office Action (paper no. 31).

Objection(s) Withdrawn

4) The objection to the drawings made in paragraph 7 of the Office Action mailed 12/11/2000 (paper no. 11) and maintained in paragraph 5 of the Office Action mailed 06/20/02 (paper no. 23) is withdrawn in light of Applicants' submission of formal drawings filed 01/23/03 (paper no. 27), which have been approved by the Draftsperson.

5) The objection to the specification made in paragraph 7 of the Office Action mailed 06/20/02 (paper no. 23) is withdrawn in light of Applicants' amendments to the specification.

Rejection(s) Moot

6) The rejection of claims 54 and 55 made in paragraph 18 of the Office Action mailed 06/20/02 (paper no. 23) under 35 U.S.C § 101 (utility) and 35 U.S.C § 112, first paragraph, is moot in light of Applicants' cancellation of the claims.

7) The rejection of claim 54 made in paragraph 20 of the Office Action mailed 06/20/02 (paper no. 23) under 35 U.S.C § 112, first paragraph, as being non-enabled, is moot in light of Applicants' cancellation of the claim.

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8) The rejection of claim 54 made in paragraph 21(d) of the Office Action mailed 06/20/02 (paper no. 23) under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

9) The rejection of claim 55 made in paragraph 23 of the Office Action mailed 06/20/02 (paper no. 23) under 35 U.S.C § 102(b) as being anticipated by Halter *et al.* (*EMBO J.* 8: 2737-2744, 1989) or Pohlner *et al.* (*Nature* 325: 458-462, 1987), is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

10) The rejection of claim 39 made in paragraph 18(a) of the Office Action mailed 05/17/01 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn.

11) The rejection of claims 50-52, which depend from claim 39 made in paragraph 18(b) of the Office Action mailed 05/17/01 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn.

12) The rejection of claims 39 and 50-52 made in paragraph 15 of the Office Action mailed 06/20/02 (paper no. 23) under 35 U.S.C. 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the base claim.

13) The rejection of claim 37 made in paragraphs 21(a) and 21(c) of the Office Action mailed 06/20/02 (paper no. 23) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

14) The rejection of claims 38 and 39 made in paragraph 21(b) of the Office Action mailed 06/20/02 (paper no. 23) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn.

15) The rejection of claims 37-39 and 48-52 made in paragraph 18 of the Office Action mailed 06/20/02 (paper no. 23) under 35 U.S.C § 101 (utility) and 35 U.S.C § 112, first paragraph, is withdrawn upon further consideration. The Jackson Declaration filed 01/23/03 under C.F.R § 1.132 has been considered.

16) The rejection of claims 37 and 50-52 made in paragraph 19 of the Office Action mailed 06/20/02 (paper no. 23) under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn in light of Applicants' amendment to the base claim.

17) The rejection of claims 50-52 made in paragraph 21(f) of the Office Action mailed 06/20/02

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(paper no. 23) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants amendment to the base claim.

Rejection(s) Maintained

18) The rejection of claim 48 made in paragraph 20 of the Office Action mailed 06/20/02 (paper no. 23) under 35 U.S.C § 112, first paragraph, as being non-enabled, is maintained for reasons set forth therein.

19) The rejection of claims 48 and 49 made in paragraph 21(d) of the Office Action mailed 06/20/02 (paper no. 23) under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein.

20) The rejection of claim 50 made in paragraph 21(e) of the Office Action mailed 06/20/02 (paper no. 23) under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

21) Claims 37, 39 and 50-52 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

It is noted that claims 37 and 39 do not structurally identify the non-meningococcal NGSP nucleic acid and the neisserial nucleic acid respectively, by a sequence ID number.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states: ‘Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed’. See page 1117. The instant specification provides written description for a gonococcal nucleic acid molecule of the nucleotide sequence SEQ ID NO: 3 encoding a gonococcal polypeptide of SEQ ID NO: 4, or a nucleotide sequence that hybridizes under the recited stringency conditions to the gonococcal nucleic acid, SEQ ID NO: 3. However, since the recited NGSP nucleic acid is not structurally identified by a SEQ ID NO in the instant claims, the nucleic acid claimed in claim 37 encompasses a broad class of nucleic acid molecules that encode any non-meningococcal non-cytosolic polypeptide having a molecular weight of ‘about’ 40 kD to 55 kD.

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Similarly, the nucleic acid claimed in claim 39 encompasses a nucleic acid encoding a polypeptide from any species of *Neisseria*. However, the instant specification lacks adequate written description for the structural composition of a nucleic acid molecule other than that of a non-meningococcal neisserial species, *Neisseria gonorrhoeae*. Other than the nucleotide sequence of SEQ ID NO: 3 which encodes the gonococcal NGSP polypeptide of SEQ ID NO: 4, the specification lacks adequate written description for the structure or other relevant identifying characteristics for the broad class of the nucleic acids currently claimed in the instant claims. The specification fails to teach the structure or relevant identifying characteristics of a representative number of nucleic acid species encoding a representative number of neisserial NGSP polypeptides that specifically bind to an antibody specific to the polypeptide (i.e., SEQ ID NO: 4) encoded by the nucleotide sequence of SEQ ID NO: 3. A skilled artisan cannot envision the precise structure of all, or a representative number of the nucleotide sequences encompassed in the claims by their chemical structure. Conception cannot be achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is a part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. One cannot envision what has not been conceived and described. Therefore, only the nucleic acid having the nucleotide sequence of SEQ ID NO: 3 encoding the gonococcal NGSP polypeptide of SEQ ID NO: 4 meets the written description provisions of 35 U.S.C § 112, first paragraph.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

22) Claims 39 and 50-52 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 39 is vague, confusing and/or redundant in the recitation 'the sequence of nucleotide sequence SEQ ID NO: 3'. It is suggested that Applicants replace the recitation with the nucleotide sequence of SEQ ID NO: 3--.

(b) Claim 39 includes the recitation 'Ficoll' which is recognized in the art as a trade name. See section [0009] of Tsukada (US 2002/0149763 A1). Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218

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USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe Ficoll, accordingly, the identification/description is indefinite. It is noted that the specification does not precisely identify 'Ficoll'.

(c) Claims 50-52, which depend directly or indirectly from claim 39, are also rejected as being indefinite because of the indefiniteness or vagueness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

23) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

24) Claims 39 and 48-52 are rejected under 35 U.S.C. § 102(e) as being anticipated by Ruelle (WO 99/55872 - Applicants' IDS).

Ruelle taught an isolated *Neisseria* polynucleotide having long stretches of structural sequence identity with the instantly recited SEQ ID NO: 3, its use as a hybridization probe, and vectors and host cells comprising the same. See the attached sequence search report and the abstract therein; and pages 9-20 of Ruelle. That the prior art polynucleotide, with as high as more than 70% sequence identity to the instantly recited SEQ ID NO: 3, hybridizes with SEQ ID NO: 3 under the recited conditions, is inherent from the teachings of Ruelle. Ruelle taught an isolated *Neisseria* polynucleotide that encodes a more than 100 amino acid-long polypeptide showing structural sequence identity with the polypeptide encoded by the instantly recited SEQ ID NO: 3. See the attached second sequence search report. That such a long polypeptide encoded by the prior art polynucleotide contains an antigenic epitope and binds specifically with an antibody specific to a

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polypeptide encoded by SEQ ID NO: 3 is inherent from the teachings of Ruelle. A vaccine composition comprising the prior art polynucleotide is used for prophylactic or therapeutic purposes (see page 17; and claim 22).

Claims 39 and 48-52 are being anticipated by Ruelle.

25) Claims 37, 39 and 48-52 are rejected under 35 U.S.C. § 102(e) as being anticipated by Fraser *et al.* (WO 99/57280 - Applicants' IDS).

Fraser *et al.* taught an isolated *Neisseria gonorrhoeae* polynucleotide, SEQ ID NO: 2967, having a long stretch of >1100 contiguous nucleotide bases identical with the instantly recited SEQ ID NO: 3, vectors, host cells and a vaccine composition comprising the same. See the attached sequence search report; claims, especially claims 6-15; pages 1389 and 1390 and pages 9-20 of Fraser *et al.* That the prior art polynucleotide having as high as more than 89% sequence identity to the instantly recited SEQ ID NO: 3 hybridizes with SEQ ID NO: 3 under the recited conditions is inherent from the teachings of Fraser *et al.* Fraser's polynucleotide encodes a >450 amino acid-long polypeptide which shows structural sequence identity with the polypeptide encoded by the instantly recited SEQ ID NO: 3. See the attached second sequence search report. That such a long polypeptide encoded by the prior art polynucleotide contains an antigenic epitope and binds specifically with an antibody specific to the polypeptide encoded by the instant SEQ ID NO: 3 is inherent from the teachings of Fraser *et al.* Given the molecular weight of 46 kDa attributed to a 441 amino acid-long polypeptide 919 (see page 1317 and abstract), Fraser's 451 amino acid-long polypeptide would be expected to have a molecular weight that falls in the recited range of 'about 40 kD to about 55 kD'.

Claims 37, 39 and 48-52 are being anticipated by Fraser *et al.*

26) Claims 39 and 48-52 are rejected under 35 U.S.C. § 102(b) as being anticipated by Regnery *et al.* (WO 9531549) as evidenced by Harlow *et al.* (*In: Antibodies: A laboratory Manual*. Cold Spring Harbor Laboratory, Chapter 5, p. 76, 1988) and *Stratagene Product Catalog* (1991).

Regnery *et al.* disclosed isolated nucleic acids encoding proteins or fragments of proteins that may be used as vaccines, and vectors, host cells and a composition comprising the same (see abstract; claims drawn to nucleic acids and vectors; and pages 3, 7 and 19-21). A polypeptide encoded by a nucleotide sequence contains an at least 7 amino acid-long fragment, VTAGIVSA,

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having 100% structural identity with an at least 7 amino acid-long fragment of the polypeptide encoded by the instantly recited nucleotide sequence. See the attached sequence search report. Due to this region of 100% sequence identity, the polypeptide fragment encoded by the prior art nucleic acid would be expected to serve as an antigenic epitope or an immunogen and bind specifically to a polypeptide encoded by SEQ ID NO: 3, because the art recognizes that the smallest peptides that elicit antibodies which bind to the original full length protein are 6 amino acids in length. See first sentence under 'Size of the Peptide' on page 76 of Harlow *et al.* That the prior art 24 nucleotide base-long polynucleotide having perfect sequence identity with a fragment of the instantly recited nucleic acid, SEQ ID NO: 3, hybridizes with SEQ ID NO: 3 under the recited conditions is inherent from the teachings of Regnery *et al.*, since the art recognizes that oligonucleotides as short as 9 base-long are of sufficient size to meet the claim limitation "nucleotide sequence that hybridizes" as illustrated by *Stratagene Product Catalog* (1991). See the attached relevant pages from the Catalog.

The teachings of Regnery *et al.* anticipate the instant claims. Harlow *et al.* or the *Stratagene Product Catalog* is **not** used as a secondary reference in combination with Regnery *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Regnery *et al.* with the unrecited limitation(s) being inherent in view of what is known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

Claims 39 and 48-52 are anticipated by Regnery *et al.*

Remarks

27) Claims 37, 39 and 48-52 stand rejected. Claims 38 and 56 are free of prior art currently of record and are allowable.

28) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

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29) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER